

Attorney Docket No.: 9391-2  
Application No.: 10/085,526  
Filed: February 26, 2002  
Page 3 of 15

This listing of the claims replaces all prior versions in the application.

**Listing of Claims:**

1. (Currently Amended) Resorbable bone replacement and bone formation material (~~augmentation material~~) based on porous  $\beta$ -tricalcium phosphate ( $\beta$ -TCP), ~~which can be~~ produced by

(a) baking a phosphate powder of a chemical composition having the residue on baking of which yields theoretically chemically pure tricalcium phosphate;

(b) forming blanks having microporosity using the baked  $\beta$ -tricalcium phosphate ( $\beta$ -TCP); and

(c) providing the baked blanks with generally tubular pores, wherein

the  $\beta$ -tricalcium phosphate ( $\beta$ -TCP) is baked at least twice and especially at least three times and the formation of the thermodynamically stable adjacent phases of  $\beta$ -TCP is prevented inhibited by, wherein the method further comprises:

(i) powdering a the presynthesis product obtained according to step (a),

(ii) optionally baking the powdered presynthesis product together with phosphate powder according to step (a) and powdering the material obtained and optionally repeating step (ii) at least once; ~~or more than once,~~

(iii) compressing the powdered product obtained in step (i) or step (ii) ~~together with phosphate powder according to step (a)~~ to form the blanks of step (b) and subjecting the blanks formed to final ceramic baking; and

(iv) subjecting the ~~compressed or~~ baked blanks, at least about 99.5% of which consists of pure  $\beta$ -tricalcium phosphate ( $\beta$ -TCP), to step (c) ~~(b)~~.

2. (Currently Amended) Formation material according to claim 1, wherein the formation material has chemical and crystalline purity, the a ~~fabrie~~ structure, the

Attorney Docket No.: 9391-2  
Application No.: 10/085,526  
Filed: February 26, 2002  
Page 4 of 15

microporosity and the macroporosity ~~that of the augmentation material~~ make possible rapid, foreign-body-reaction-free, biochemically orientated integration and resorption in bone.

3. (Currently Amended) Resorbable bone replacement and bone formation material according to claim 1, which can be produced by

(i) ~~starting from a presynthesis product obtainable by~~ baking phosphate powder of a chemical composition having a ~~the~~ residue on baking of which yields theoretically chemically pure tricalcium phosphate as a presynthesis product, and powdering that presynthesis product;

(ii) ~~optionally baking the powdered presynthesis product together with phosphate powder according to step (i) and powdering the material obtained and optionally repeating step (ii) at least once or more than once;~~

(iii) compressing the powdered product obtained in step ~~(i) or step (ii) together with phosphate powder according to step (i)~~ to form shaped blanks having microporosity and subjecting the blanks formed to ~~final~~ ceramic baking; and

(iv) providing the compressed or baked blanks with generally tubular macropores.

4. (Previously Presented) Formation material according to claim 1, obtainable by baking at a temperature below 1200°C in the  $\beta$ -tricalcium phosphate ( $\beta$ -TCP) phase region.

5. (Currently Amended) Formation material according to claim 1, obtainable by using in step (ii) and/or step (iii) from 1 to 50% by weight, especially from 1 to 25% by weight, phosphate powder, the weight (based on the total weight of phosphate powder and already baked material.)

6. (Currently Amended) Formation according to claim 1, wherein the baked  $\beta$ -tricalcium phosphate ( $\beta$ -TCP) comprises sintered primary particles, wherein the blanks have a generally uniform sintered structure ~~with has a uniform,~~ interconnected microporosity having

Attorney Docket No.: 9391-2  
Application No.: 10/085,526  
Filed: February 26, 2002  
Page 5 of 15

pore widths in the region of from about 2  $\mu$ m to 15  $\mu$ m and/or ~~a~~ the matrix of the  $\beta$ -tricalcium phosphate ( $\beta$ -TCP) primary particles ~~augmentation material that~~ is tightly sintered to microporosity, especially with microparticles that are loosely bound in the sintered structure and/or phagocytosable, having a diameter of max. 15  $\mu$ m, being absent.

7. (Currently Amended) Formation material according to claim 1, wherein the baked blanks comprise a microporosity of at least about 20% by volume or more, preferably from 20 to 40% by volume, and especially 30% by volume or more, based on the overall porosity, the overall porosity defined by ~~(consisting of micro- and macro-porosity)~~.

8. (Currently Amended) Formation material according to claim 1, wherein the compressing step comprises ~~obtainable by~~ providing the compressed blank with tubular pores with the aid of a compression mould of optionally more than one part.

9. (Currently Amended) Formation material according to claim 1, wherein the providing the baked blanks with generally tubular pores comprises ~~obtainable by~~ providing the baked blank with generally tubular pores by ~~means of~~ milling and/or drilling.

10. (Currently Amended) Formation material according to claim 1, wherein ~~the formation material~~ the blanks ~~is~~ are in block form having a block surface, with 2- or 3-dimensionally oriented macroscopic generally tubular pores passing through each block, which are in each case arranged generally perpendicular to the block surface and/or to an imaginary plane laid through the block or against the block and form an interconnecting system of tubular pores.

11. (Previously Presented) Formation material according to claim 10, wherein a block intended for implantation, together with its tubular pores, can be so oriented for implantation

Attorney Docket No.: 9391-2  
Application No.: 10/085,526  
Filed: February 26, 2002  
Page 6 of 15

or on processing prior to implantation that at least one direction of orientation of the tubular pores corresponds to a biomechanically or biofunctionally intended direction of growth.

12. (Currently Amended) Formation material according to claim 1, wherein the tubular pores that have radii in the region of from about 100  $\mu\text{m}$  to about 2000  $\mu\text{m}$  and especially from 200 to 2000  $\mu\text{m}$ .

13. (Currently Amended) Formation material according to claim 1, wherein the blanks are formation material, present in block form, is each block comprising penetrated by the tubular pores that are spaced apart at a defined spacing with respect to one another, especially that a spacing that corresponds to a wall thickness of less than not more than from about 1500 to 4000  $\mu\text{m}$  and especially from 2000 to 3000  $\mu\text{m}$ .

14. (Currently Amended) Formation material according to claim 1, wherein the blanks have an overall porosity, defined by (consisting of micro- and macro-porosity), of more than about 50% by volume.

15. (Currently Amended) Formation material according to claim 1, wherein a the blanks with the generally tubular pores have a macroporosity of from 25 to 50% by volume, and especially from 30 to 40% by volume, based on the overall porosity, defined by (consisting of micro- and macro-porosity).

16. (Currently Amended) Formation material according to claim 1, wherein the blanks have a block form that is a simple geometric shape, especially that of a cube, cuboid, taper, cone or disc.

17. (Currently Amended) Formation material according to claim 1, wherein it is the blanks define a semi-finished product, especially configured to allow for subsequent

Attorney Docket No.: 9391-2  
Application No.: 10/085,526  
Filed: February 26, 2002  
Page 7 of 15

mechanical processing, ~~preferably~~ and/or for individual adaption in the case of bone defect in mouth or jaw medicine, orthopaedic surgery or trauma surgery.

18. (Currently Amended) Formation material according to claim 11, wherein the blank material is compressed, especially baked and/or sintered, only to a degree such that it can be processed using medical or dentistry tools available to a the practitioner, ~~especially using a rasp, file, scalpel or dentist's instrument.~~

19. (Currently Amended) Formation material according to claim 11, wherein the block it has been brought into the form of an individual prosthesis with the aid of a medical CAD/CAM method.

20. (New) Formation material according to Claim 16, wherein the simple geometric shape is generally one of a cube, a tapered body, a rectangular box-like body, a wedge, a cone, a cylinder or a disc.

21. (New) A method of producing resorbable bone replacement and bone formation material, comprising:

- (i) baking phosphate powder of a chemical composition having a residue on baking which yields theoretically chemically pure beta-tricalcium phosphate as a presynthesis product, and powdering that presynthesis product;
- (ii) baking the powdered presynthesis product and powdering the baked material obtained and optionally repeating step (ii) at least once;
- (iii) compressing the powdered product obtained in step (ii) to form blanks;
- (iv) baking the blanks, wherein the compressed baked blanks have a generally uniform sintered structure with interconnected microporosity having pore widths between about 2  $\mu\text{m}$  to about 15  $\mu\text{m}$ ; and
- (v) providing the compressed baked blanks with generally tubular macropores.

Attorney Docket No.: 9391-2  
Application No.: 10/085,526  
Filed: February 26, 2002  
Page 8 of 15

22. (New) A method of fabricating a biocompatible resorptive and/or resorbable bone augmentation product, comprising:

compressing granular and/or powder form  $\beta$ -tricalcium phosphate into a shaped body;  
then  
heating the compressed  $\beta$ -tricalcium phosphate shaped body; then  
forming macropores in the shaped body.

23. (New) A method according to Claim 22, wherein the shaped body is a blank, the method further comprising forming the blank into a desired configuration after the compressing and heating steps.

24. (New) A method according to Claim 22, further comprising, before said compressing step, sintering the granular and/or powder form  $\beta$ -tricalcium phosphate at least once.

25. (New) A method according to Claim 23, wherein the compressing step employs granular and/or powder form  $\beta$ -tricalcium phosphate material that has been exposed to heat a plurality of times at a temperature below 1200 °C but sufficient to sinter the  $\beta$ -tricalcium phosphate material to inhibit the formation of thermodynamically stable adjacent phases of  $\beta$ -tricalcium phosphate.

26. (New) A method according to Claim 22, wherein the heating step comprises baking the shaped body to a predetermined temperature for a predetermined time.

27. (New) A method according to Claim 22, wherein the shaped body comprises a sintered structure of interconnected micropores with securely attached microparticles of the granular and/or powder form  $\beta$ -tricalcium phosphate.

Attorney Docket No.: 9391-2  
Application No.: 10/085,526  
Filed: February 26, 2002  
Page 9 of 15

28. (New) A method according to Claim 22, wherein the shaped body comprises  $\beta$ -tricalcium phosphate material having primary particles that have a particle diameter size that is greater than about 15 $\mu$ m and are sintered together and to define an interconnected matrix of micropores.

29. (New) A method according to Claim 22, wherein the heating step comprises baking the shaped body, and wherein the forming the macropores step comprises introducing generally tubular apertures into and/or through the baked shaped body.

30. (New) A method according to Claim 22, wherein the forming macropores step comprises machining, milling and/or drilling generally tubular apertures into the shaped body.

31. (New) A method according to Claim 22, wherein the shaped body has a microporosity of about at least 20% by volume prior to the forming macropores step.

32. (New) A method according to Claim 31, wherein the forming macropores step comprises inserting sufficient macropores in the shaped body to provide a macroporosity of at least about 20% of the total porosity of the shaped body.

33. (New) A method according to Claim 22, wherein the forming macropores step comprises drilling and/or milling elongate generally tubular macropores into the shaped body.

34. (New) A method according to Claim 22, wherein the forming macropores step comprises inserting a plurality of the macropores into the shaped body to be aligned generally parallel to each other and spaced apart so that the material thickness therebetween is about 3 mm or less.

Attorney Docket No.: 9391-2  
Application No.: 10/085,526  
Filed: February 26, 2002  
Page 10 of 15

35. (New) A method according to Claim 22, wherein the heating step comprises sintering the shaped body.

36. (New) A method according to Claim 23, further comprising configuring the shaped body with the macropores into a custom implantable shape at a use site.

37. (New) A method according to Claim 22, wherein the forming macropores step comprises inserting generally tubular apertures therein so that a plurality of the tubular apertures extend in a generally common direction through the shaped body so that, in position, the plurality of tubular apertures can be aligned with a primary growth direction of adjacent host bone in a target implant site.

38. (New) A method according to Claim 23, wherein the shaped body is a blank having the general shape of at least one of a cube, a cuboid, a tapered body, a wedge, a cone or a disc.